ALLIANCE
MEDICAL CORPORATION

10232 South 51st Street
Phoenix, Arizona 85044

TEL 480.763.5300
FAX 480.763.5310
Toll Free 888.888.3433
www.alliance-medical.com

February 11, 2002

BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

Alliance Medical Corp. (Alliance)[1] respectfully submits this petition under Section 515 of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 10.30. The purpose of this petition is to request that the Commissioner of Food and Drugs (the Commissioner) modify the February 14, 2002, deadline for Food and Drug Administration (FDA) clearance of premarket notification submissions (510(k)s) for Class II reprocessed devices, as required by the August 14, 2000, "Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (Guidance). Alliance requests that this deadline be modified to extend until August 14, 2002. Alliance further requests that the agency permit continued marketing during FDA review of completed 510(k)s.

Due to the urgency of this petition, Alliance will assume it to be denied if FDA has not replied by February 14, 2002.

A. Actions Requested

Alliance requests that FDA modify the February 14, 2002, deadline for agency clearance of 510(k)s for Class II reprocessed devices and that it be extended until August 14, 2002. Alliance further requests that FDA allow continued marketing during agency review of the completed 510(k)s.

02P-0061

CP3

[1] Alliance is a third-party reprocessor of medical devices labeled for single use, headquartered in Phoenix, Arizona.

B. Statement of Grounds

FDA's February 14, 2002, 510(k) clearance deadline is unreasonably short and should be lengthened.

As a threshold matter, Alliance observes that FDA gave the reprocessing industry a mere 12 months in which to prepare 510(k) submissions for a multitude of products. Alliance worked diligently and spent hundreds of thousands of dollars to meet this unreasonable deadline – and, ultimately, Alliance succeeded. On or before the August 14, 2001 deadline, Alliance submitted numerous 510(k) submissions. Having accomplished this nearly impossible task, Alliance is now faced with the disturbing reality that it still may be forced off the market because FDA is unable to meet its February 14, 2002 clearance deadline.

Alliance strongly objects to the notion that its ability to market should be dependent upon FDA clearing its 510(k) submissions within a pre-determined timeframe. Indeed, this approach departs dramatically from prior agency practice. Rather, the agency historically has imposed premarket submission deadlines, and has permitted marketing for as long as it takes for FDA to complete its review. As one example, in 1994, when FDA determined that software products used by blood establishments to manage donor information were subject to regulation as medical devices, the agency initially provided an entire year for manufacturers to submit premarket approval applications (PMA) or 510(k)s, and the agency subsequently extended the submission deadline for another year. See 59 Fed. Reg. 44, 991 (Aug. 31, 1994); 60 Fed. Reg. 51, 802 (Oct. 3, 1995). The manufacturers were then permitted to stay on the market during FDA review of the submissions.

It clearly was unrealistic to expect that FDA would complete its review of all reprocessed device 510(k)s within six months. Because of agency resource constraints, delays in reviewing and responding to 510(k)s are common, and, given that FDA reviewers have no experience with submissions for reprocessed devices, delay was inevitable. Moreover, in a number of cases, the agency has "changed its mind" midstream regarding what Alliance must include in its submissions. In addition, FDA has been very slow in issuing important guidance concerning 510(k) submission requirements. As one example, the agency did not provide labeling guidance relevant to 510(k) submissions until July 30, 2001 – only two weeks before the 510(k) submission deadline. These agency delays and vacillations have further slowed the 510(k) review process – and they further highlight the unfairness of holding Alliance, and the entire reprocessing industry, hostage to an arbitrary agency clearance deadline.

If there were evidence that protection of the public health warranted requiring such a compressed timeframe, Alliance would support FDA's February 14, 2002 deadline. However, the facts clearly show that no such public health concern exists. Indeed, FDA itself acknowledges that it

has "been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."[2]

In fact, Alliance is concerned that the public health may well be harmed if FDA maintains the February 14, 2002 deadline. Reprocessing allows hospitals to achieve significant cost savings, while maintaining the highest standards of patient care. As Dr. Stephen Hammill, Director of Electrocardiography and Electrophysiology Laboratories at the Mayo Clinic, wrote in a June 23, 1999 letter to Senator Paul Wellstone (D-MN):

> For more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection. Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures . . . . Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible.[3]

The bottom line is that the reprocessed devices in question are being safely used by the nation's top hospitals. They will not suddenly become "unsafe" on February 15, and the reprocessing industry should not be forced to incur devastating economic loss because FDA has been unable to meet an arbitrary 510(k) clearance deadline.

Conclusion

The approach laid out in the Guidance is unprecedented. Proponents of additional regulatory burdens for reprocessors argued that original equipment manufacturers and reprocessors should have a "level playing field." By providing reprocessors such a limited time to prepare, submit, and receive FDA clearances, FDA has created a "playing field" where no reprocessor has a fair shot at "winning." When reprocessing loses, patients and hospitals lose too. Alliance has worked in good

---

[2] See attached Letter from Dr. David Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, Esq., Counsel to the Medical Device Manufacturers Association (October 6, 1999) (Attachment A).

[3] See Letter from Stephen C. Hammill, M.D., Professor of Medicine and Director of Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, Rochester, Minnesota to Senator Paul Wellstone (June 23, 1999).

faith to meet the Guidance requirements, though Alliance suspected on August 14, 2000 that strict adherence to these timeframes would be impossible.

Objections to the timeframes through its trade association, the Association of Medical Device Reprocessors (AMDR), and in numerous meetings and phone calls with the agency, have proven fruitless.[4] This Citizen Petition now asks FDA to modify the February 14, 2002, 510(k) clearance deadline to extend until August 14, 2002, and to permit continued marketing during agency review of completed 510(k)s.

C. Environmental Impact

This petition is entitled to a categorical exclusion under 21 C.F.R. § 25.30 and § 25.31.

D. Economic Report

Alliance will submit an economic analysis upon request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views upon which the petitioner relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Rick Ferreira CPO

R.M. Ferreira
Chief Executive Officer
Alliance Medical Corp.

RMF:la
Enclosures
cc: Dr. David Feigal
Phil Philips
Larry Spears

[4] For a more detailed review of these issues, see AMDR Comments (Attachment C).